Comment 46 BioIndustry Association/Andrew Sheard

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To: mark.nagumo@uspto.gov
Subject: BIA's Comments on "Utility" Guidelines

1. These comments on the Revised Utility Examination Guidelines ("the Guidelines") are submitted on behalf of the BioIndustry Association ("BIA"). The BIA is the trade association of the bioscience industry in the United Kingdom and has over 200 members. As users of the US patent system and other patent systems in the industrialised world, its members are keen to see fair and proportional patent protection on a level playing field. BIA members are active in licensing their products to US-based companies and exporting technology to the US, as well as participating in flows in the opposite direction.

2. The BIA broadly welcomes the revised interim guidelines. In particular, it welcomes the explicit guideline that a claimed invention must have a specific and substantial utility, so that, for example, "the use of a complex invention as landfill" would not satisfy 35 USC 101.

3. The BIA also accepts and welcomes the confirmation that a utility must be "credible". However, we caution against any return to the period when the level of proof required to satisfy the utility requirement, for medicaments for human use, was in danger of being interpreted, by some office personnel at least, as being essentially equivalent to the level of proof of efficacy demanded by the regulatory authorities before a medicinal product may be marketed. Haveing said that, we do not detect any intention along these lines in the guidelines as written.

Respectfully submitted

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